REMARKS

Rejection of the claims under 35 USC § 102:

Claims 1-6 and 9-12 have been rejected under 35 U.S.C. 102(b) as being anticipated by either one of Liu *et al.* (1999) or Zhang *et al.* (1999). Applicants have amended the claims to obviate the rejection. Specifically, Applicants have amended the claim 1 and added new claims 34 and 35 to recite steps that result in manipulative differences distinguishable from the prior art.

Claims 25-27 have been rejected under §102(b) as being anticipated by or Hurpin *et al.* Applicants have amended the claims to obviate the rejection. Hurpin *et al.* observed an immune response after injection of an intact virus into the tail vein of mice. Applicants' have amended the claim specify that the nucleic acid is either naked nucleic acid or associated with a non-viral particle. Support for the amendment can be found in the specification on page 27 (last paragraph), on pages 12-13, and examples 3 and 5 on pages 39-40. Hurpin *et al.* did not teach injection of a nucleic acid that was not associated with an intact virus.

Rejection of the claims under 35 USC 103:

Claim 7 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* and Zhang *et al.* in view of Smyth-Templeton *et al.* As discussed in the previous section, it is Applicants opinion that the amendment obviates this §103 rejection.

Rejection of the claims under 35 USC 112:

Claims have been rejected under 35 U.S.C. 112, as being indefinite. The action states that it is unclear whether individuals in a majority of all mammalian species or a majority of individuals within a single mammalian species is intended. Applicants have amended the claims to recite "generating the immune response in a majority of individual mammals injected." Applicants have used their procedure to generate immune responses in mice, rats, and rabbits. In addition, Applicants have observed that their gene delivery process is equally effective in delivering expressible genes in dog, pig and primate (immune response has not been assayed in these animals). However, because the gene delivery works equally well in all mammal species tested, it is reasonable to expect that generation of immune response will be equally effective in all mammals. Applicants have submitted, with this reply, a declaration

under 37 CFR 1.132 showing immune response in rat and rabbit and gene delivery and expression in dog, pig and primate.

Claims have been rejected under 35 U.S.C. 112, as containing new matter, for reciting "a majority of mammals". Applicants respectfully disagree. Applicants have stated that their invention is intended for genetic vaccination, antibody production, and isolation of antibody producing cells. Each of these stated intentions, especially genetic vaccination, would be readily recognized by those skilled in the art, as requiring that the process be effective in a majority of the mammals treated. Therefore, it is Applicants opinion that generating an immune response in a majority of individual mammals is inherently supported in the specification. In addition, as the Examiner points out, Applicants demonstrate the effectiveness of their invention in 8 out of 8 mice in example 8. In addition, Applicants submit, with this reply, a declaration under 37 CFR 1.132, showing similar results in rats and rabbits.

Claim 25 has been rejected under 35 U.S.C. 112, as containing new matter, for reciting a "non-viral nucleic acid". Applicants have amended the claims to obviate the rejection as described above in response to the 102 rejection over Hurpin *et al.*

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1-7, 9-12, 25-27 and 34-35 should be allowable.

Respectfully submitted,

Kirk Ekena Reg. No. 35,909
Mirus Bio Corporation
505 South Rosa Road
Madison, WI 53719
608-238-4400

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: 23 Nov. 2005 .

Kirk Ekena